

# Data Transfer Protocol for IeDEA Multi-regional Collaborations

Originally approved by the IeDEA Executive Committee on Thursday August 16, 2012

Revised by IeDEA Data Harmonization Working Group on April 14, 2015

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## Summary:

This document describes a protocol for IeDEA regional data coordination centers for exchanging data in support of multi-regional analyses. According to the proposed protocol and when applicable, all multi-regional data requests and data transfers will reference and conform to a single **IeDEA Data Exchange Standard (IeDEA-DES)**. The IeDEA Data Harmonization Working Group (DHWG) will be responsible for publishing the definitions that constitute the IeDEA-DES. When possible, the IeDEA-DES will be based on the HIV Cohorts Data Exchange Protocol (HICDEP). When there is a need for data elements that are not represented by the IeDEA-DES, then the DHWG will work with the authors of the concept sheets and with relevant IeDEA working groups to define and append these new data elements into the IeDEA-DES. This will minimize the future duplication of effort by the regional data managers preparing these data elements. Interested investigators from IeDEA will work with the HICDEP organization on behalf of IeDEA to contribute the definitions of the new data elements for possible inclusion in future HICDEP versions (www.hicdep.org).

## Scope:

* This protocol will apply to all multi-regional concept sheets approved by the IeDEA Executive Committee (IeDEA-EC) after the adoption of this protocol and subsequent revisions.
* The data definitions (IeDEA-DES) referenced in this protocol are only applicable to data exchange among regions or among multiple regions with collaborators external to IeDEA. Data definitions such as table structure, variable names, and variable codes adopted by the IeDEA regions for **intra-regional data exchange and storage are under the autonomy of the regions and remain outside the scope of this protocol**.
* This protocol provides Standard Operating Procedures (SOPs) for how multi-regional concept sheets will define and code the data elements that they request. **This protocol specifies how data will be requested and transferred, and not what data should be requested and transferred**. The concept sheet investigator will decide what data elements in the IeDEA-DES to request from other regions. The IeDEA regions maintain autonomy in choosing whether to participate fully, partially, or not at all in any given approved multi-regional study.

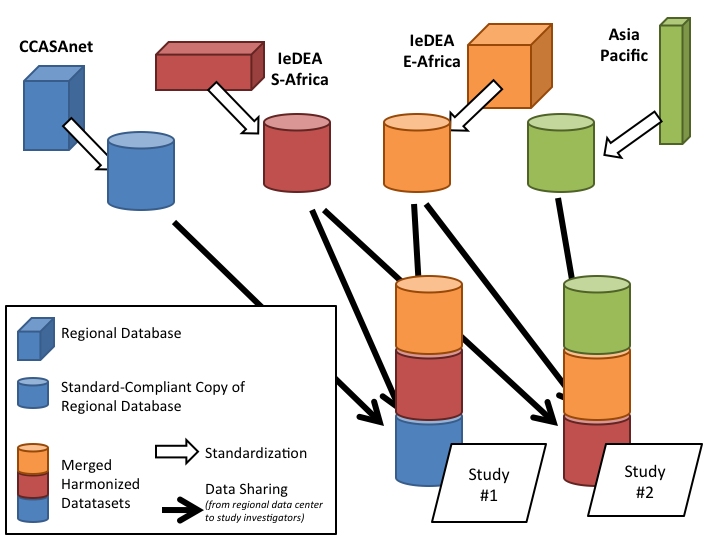
## Components of the IeDEA Data Transfer Protocol:

1. Standard procedures for data request and transfer: specified by this document
2. The IeDEA Data Exchange Standard: a reference document listing tables, variables, and codes that will be used to format the data for inter-regional exchange. It will be published and updated by the IeDEA DHWG as an appendix to this document and will be available via the IeDEA.org website.

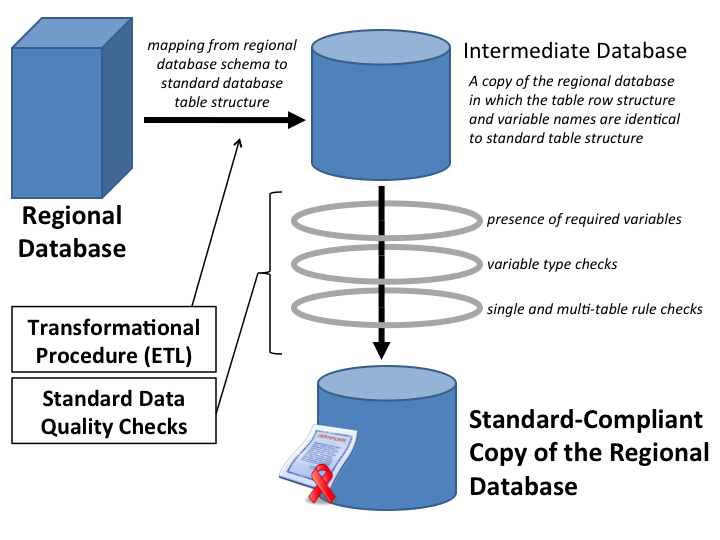
## Procedure for Data Request and Transfer:

### Overview

Multi-regional concept sheets are subject to IeDEA-EC review and approval. The multi-regional concept sheets typically include a Standard Operating Procedure (SOP) that provides a definition of the requested data elements for that particular study. **After the adoption of this protocol, concept sheet principal investigators (CS-PIs) will start using the IeDEA-DES as the official standard for specifying the requested data elements.** After approval of a specific concept sheet, the IeDEA regions will decide whether to participate and contribute data. Regional participation can be partial. For example, a region may elect to send data from only a subset of the sites within a region or for only a subset of the requested data elements. The regional data manager (RDM) – or a regional data contact person – will then transfer a copy of that region’s data or a subset thereof using the IeDEA-DES-compliant data elements chosen by the CS-PIs.



This figure highlights the importance of standard compliance for efficient and seamless data harmonization. In the process depicted here, every regional data coordination center creates a standard-compliant copy of their regional database. This procedure can take place once, on a pre-determined schedule, or as the need arises depending on regional preference and capacity. The regional data coordination centers retain control of their local standard-compliant copy. Once an external request for data sharing is approved, the regional data managers share all or part of the standard-compliant version of their database. The work is also minimized for the multi-regional study investigators because their data management task is reduced to "stacking" or merging multiple datasets of identical table structure. Most of the data harmonization effort occurs early on in the form of one-time data standardization overhead.



Data standardization is a multi-step process that involves both table transformation and data quality checks. The table transformation step takes as input data that is formatted according to the native regional database schema. The table structure (record structure, variable names) is transformed to match the data exchange standard. For coding variables, the coded values are mapped from the native to the standard coding scheme. This transformational step is similar to the Extraction, Transformation, and Loading (ETL) procedures that are commonly employed when merging databases. For seamless data harmonization to occur, conformance to syntactic structure (e.g. variable name) is not enough. The data exchange standard specifies a set of data quality constraints that are reasonable to expect for meaningful interpretation of the data to occur. For example, there is a minimum set of variables that will be needed to ensure that records are correctly and uniquely identified (e.g. unique patient id, site id, basic demographics) or for drug information to be unambiguously computed (e.g. a start date is required to accompany all medication records). Some of those semantic checks span multiple tables. For example, no entry is allowed in pregnancy-related tables unless the sex in the demographics table is "female" for that patient, or if a date of death is recorded in the follow-up table, then no subsequent observation is allowed in any other table for that patient.

### Role of Concept Sheet Principle Investigators (CS-PIs)

The CS-PIs (acting as or working with the “concept leads”) shall include a clear description of the data elements they are requesting for their study. This includes an enumeration of the requested tables and variables and a specification of those that are essential for participation in the study and those that are optional. If the data elements they are requesting are present within the IeDEA-DES tables, then the CS-PIs will list these tables/variables as-is in the concept sheet SOP. Otherwise, the CS-PIs will work with the DHWG to define a format for the additional data elements that they are requesting (see below).

The CS-PIs will receive the data as specified by the concept sheet SOP from the regional data managers. They and their concept analysis teams will be responsible for merging the data from the different participating regions, for submitting any record-level queries to the regions, and for preparing the merged data for final analysis. They should also expect to receive a clear description from the RDMs of the attributes of the shared data such as the date the database was closed, and the criteria for inclusion of records.

### Role of Regional Data Managers (RDMs)

The RDMs main focus is to support the data operations within each region. Typically the data from the region’s participating sites are merged into a master database for regional analyses. The RDMs are also responsible for preparing data for external (to their region and sometimes to IeDEA) collaborators based on approved multi-regional concept sheets. All external requests for data should use a consistent format that is based on the IeDEA-DES. If their sites have elected to participate in a multi-regional study, they will be responsible for sharing a copy of their database (or a subset thereof) that is IeDEA-DES-compliant as per that study’s SOP.

It will be left to the RDMs to decide on the best approach they want to follow for preparing the IeDEA-DES-compliant copy of their database. For example, they can generate that copy ad hoc every time their region participates in a new study. Another approach would be to construct an IeDEA-DES-compliant copy periodically (for example every year or every two years) as they build their regional master database. They can then draw and re-draw from this same IeDEA-DES-compliant copy to participate in multiple multi-regional concept proposals. This protocol does not specify the manner with which data are collected, prepared, or merged. It only specifies the structure, conventions, and data quality checks used for the data elements that the regions choose to share. The protocol also does not specify the date of closure of the shared database relevant to a data request. That will be left to the RDMs and to the regional policies. However, when sharing the data with a CS-PI, the RDMs should be prepared to clearly indicate the timeline with which the data was collected and the criteria by which the records were included.

The protocol also does not specify which data elements should be collected. It is reasonable to expect that not all data elements in a given SOP are available or sharable by all regions. In this case, the RDMs do not need to provide the tables or leave the unavailable variables blank. The approval by a region to participate in a study does not bind that region to collect and submit every data element that was requested in that study’s SOP unless that was explicitly agreed upon by the region and the CS-PI prior to the region’s decision to participate. As mentioned above, that agreement is beyond the scope of this protocol

### Role of IeDEA Data Harmonization Working Group (DHWG)

During the concept sheet proposal stage, the DHWG will work with CS-PIs to specify the IeDEA-DES data elements they require. It is reasonable to expect that the required data elements for a given study may need to be represented by tables, variables, or codes that do not exist in the IeDEA-DES. In this case, the DHWG will work with CS-PI and relevant working groups to update the IeDEA-DES to include the required definitions as described below. Future concept sheets can re-use the newly added data elements thereby minimizing the duplication of work by RDMs in the future.

After the approval of a concept sheet by the IeDEA-EC, the DHWG will catalogue and share all the data elements that were requested as part of that concept sheet. This will allow the tracking of the data elements that are most commonly used across future concept sheets. The DHWG, as well as interested members of other working group, will work with the HICDEP representatives to discuss and reconcile, when feasible, any discrepancies between the IeDEA-DES and HICDEP. Please see the sections below.

## The IeDEA Data Exchange Standard (IeDEA-DES)

### Structure of the IeDEA-DES

The IeDEA-DES is a reference document listing tables, variables within tables, and the codes that are used for standard categorical variables. It is the intention of the IeDEA network for the IeDEA-DES to be compatible when possible with the HICDEP table definitions and variable formatting conventions. The tables listed in the IeDEA-DES will be designated as:

1. **HICDEP table**: Tables designated as such will be based completely on the corresponding table in HICDEP and in effect will be adopted as-is from HICDEP.
2. **HICDEP+ table**: Tables designated as HICDEP+ will be based on corresponding HICDEP tables, but will also contain supplemental variables and codes that are not present in the HICDEP standard. As such, they provide a “superset” of the elements required for the HICDEP standard but are essentially compatible with HICDEP.
3. **Non-HICDEP**: This designation will be applied to tables that are non-HICDEP compliant. They may have been defined based on HICDEP tables with significant modifications to existing codes or variables or they may have been defined de novo by IeDEA investigators.

The DHWG will be responsible for maintaining and publishing the IeDEA-DES as it continues to evolve.

### Procedure for Updating the IeDEA-DES to Include Previously Undefined Data Elements

If a concept sheet proposes to request and analyze data elements that are not represented in the IeDEA-DES, then the DHWG will work with the CS-PIs and the relevant working groups (e.g. clinical outcomes, pediatrics, cancer, etc) to update the IeDEA-DES within 6 weeks from notification of the DHWG. When updating the IeDEA-DES, the first considerations will be whether corresponding data elements exist in the most recent version of HICDEP and whether the HICDEP representation is suitable. If HICDEP does not provide an acceptable representation for the scientific purpose of the concept sheet, then the DHWG working group (working with the CS-PIs and relevant working group) will define the appropriate data element and append that definition to the IeDEA-DES.

### Maintaining Correspondence between IeDEA-DES and HICDEP

It is the intention of the IeDEA network to align when possible with the definitions and conventions of the HICDEP standard. This cooperative effort will support a single global HIV data exchange standard when possible, promote goodwill, and simplify global analyses that merge IeDEA and other global cohort data. Interested IeDEA investigators may participate in the HICDEP discussion boards and attempt to reconcile or incorporate elements from IeDEA-DES tables designated as HICDEP+ or non-HICDEP into the HICDEP standard.

## Appendix A: IeDEA-DES Tables

Note: the Data Harmonization Working Group will be responsible for updating and publishing the most recent revisions of this section of the data transfer protocol both in printable and online format. Once tables are approved and designated as either HICDEP+ or Non-HICDEP, this document will need to provide additional documentation of the modified or additional data elements that constitute these tables.

Date last revised: February 2017 (Additions/modifications to existing tables are highlighted in orange. Coded responses highlighted in yellow represent deviations from HICDEP.)

Designations based on HICDEP version 1.100

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Table Name | Description | Not Yet Designated | HICDEP | HICDEP+ | Non-HICDEP |
| tblART | antiretroviral drugs |  |  | X |  |
| tblART\_MUM | antiretroviral medication of mother |  |  |  | X |
| tblBAS | basic Information |  |  | X |  |
| tblCANC | cancer diagnoses |  | X |  |  |
| tblCENTER | site-specific information |  |  | X |  |
| tblCEP | clinical events including serious non-AIDS conditions | X |  |  |  |
| tblDELIVERY\_CHILD | delivery information related to child |  |  | X |  |
| tblDELIVERY\_MUM | delivery information related to mother |  |  | X |  |
| tblDIS | diseases (CDC-C & WHO stage diseases) |  |  | X |  |
| tblLAB | laboratory tests |  |  | X |  |
| tblLAB\_BP | blood pressure |  | X |  |  |
| tblLAB\_CD4 | CD4 measurements |  | X |  |  |
| tblLAB\_RES | resistance testing information |  |  | X |  |
| tblLAB\_RES\_LVL\_1 | nucleoside sequence for PRO and RT | X |  |  |  |
| tblLAB\_RES\_LVL\_2 | mutations and positions of PRO and RT sequences |  | X |  |  |
| tblLAB\_RES\_LVL\_3 | resistance result |  |  | X |  |
| tblLAB\_RNA | viral assay |  | X |  |  |
| tblLAB\_VIRO | viro-/serological Tests |  |  | X |  |
| tblLTFU | death and drop-out |  |  | X |  |
| tblMED | other medications |  |  | X |  |
| tblNEWBORN | information related to newborns |  |  | X |  |
| tblNEWBORN\_ABNORM | information related to abnormalities of newborn |  |  | X |  |
| tblOVERLAP | participation in other cohorts |  | X |  |  |
| tblPREG | general pregnancy-related information |  |  | X |  |
| tblPREG\_OBS | obstetrical problems | X |  |  |  |
| tblPREG\_OUT | pregnancy outcome |  |  | X |  |
| tblPROGRAM | linking sites to programs |  | X |  |  |
| tblREFILL | prescription refills | X |  |  |  |
| tblSAMPLES | biological sample storage | X |  |  |  |
| tblVIS | visit-related information |  |  | X |  |

### tblART (Antiretroviral Medication)

**Relation to HICDEP**: HICDEP+

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| PATIENT | character (or numeric if possible) | Code to identify patient (Cohort Patient ID) |
| ART\_ID | character. see coding table for valid codings. | Represents the antiretroviral treatment |
| ART\_SD (\_A) | yyyy-mm-dd | Date of initiation of treatment |
| ART\_ED (\_A) | yyyy-mm-dd | Date of stopping of treatment |
| ART\_RS | numeric see coding table for valid codings. | Reason for stopping treatment |
| ART\_RS2 | numeric see coding table for valid codings. | Additional reason for stopping treatment |
| ART\_RS3 | numeric see coding table for valid codings. | Additional reason for stopping treatment |
| ART\_RS4 | numeric see coding table for valid codings. | Additional reason for stopping treatment |
| ART\_FORM | numeric:  1 = Tablet/capsule  2 = Syrup/suspension  3 = Combination of 1 and 2  4 = Powder  5 = Subcutaneous  6 = Intravenous  7 = Intramuscular  9 = Unknown | What formulation of the drug was given? |
| ART\_COMB | numeric:  0 = Individual drug  1 = Part of a fixed-dose combination  9 = Unknown | Was the drug given as part of a fixed-dose combination? |
| ARTSTART\_RS | numeric: see coding table | Reason for starting/receiving ART |

| **Code (Extended ATC Codes)** | **Antiretroviral Drugs** |
| --- | --- |
| J05A | ART unspecified |
| J05A-BEV | Beviramat |
| J05A-PBT | Participant in Blinded Trial |
| J05AE | PI unspecified |
| J05AE-MOZ | Mozenavir (DMP-450) |
| J05AE01 | Saquinavir (gel, not specified) |
| J05AE01-SQH | Saquinavir hard gel (INVIRASE) |
| J05AE01-SQS | Saquinavir soft gel (FORTOVASE) |
| J05AE02 | Indinavir (CRIXIVAN) |
| J05AE03 | Ritonavir (NORVIR) |
| J05AE03-H | Ritonavir high dose (NORVIR) |
| J05AE03-L | Ritonavir low dose (NORVIR) |
| J05AE04 | Nelfinavir (VIRACEPT) |
| J05AE05 | Amprenavir (AGENERASE) |
| J05AR10 | Lopinavir/Ritonavir (Kaletra). Former code: J05AE06 |
| J05AE07 | Fos-amprenavir (Telzir, Lexiva) |
| J05AE08 | Atazanavir (Reyataz) |
| J05AE09 | Tipranavir (Aptivus) |
| J05AE10 | Darunavir (TMC-114, Prezista) |
| J05AF | NRTI unspecified |
| J05AF-ALO | Alovudine |
| J05AF-AMD | Amdoxovir (DADP) |
| J05AF-FOZ | Fozivudine tidoxi |
| J05AF-LDN | Lodenosine (trial drug) |
| J05AF-RVT | Reverset |
| J05AF01 | Zidovudine (AZT, RETROVIR) |
| J05AF02 | Didanosine (ddI) (VIDEX) |
| J05AF03 | Zalcitabine (ddC) (HIVID) |
| J05AF04 | Stavudine (d4T) (ZERIT) |
| J05AF05 | Lamivudine (3TC, EPIVIR) |
| J05AF06 | Abacavir (1592U89) (ZIAGEN) |
| J05AF07 | Tenofovir (VilREAD) |
| J05AF08 | Adefovir (PREVEON) |
| J05AF09 | Emtricitabine |
| J05AF10 | Entecavir |
| J05AF11 | Telbivudine |
| J05AG | NNRTI unspecified |
| J05AG-CPV | Capravirine |
| J05AG-DPC083 | DPC 083 |
| J05AG-DPC961 | DPC 961 |
| J05AG-EMV | Emivirine (MKC442) |
| J05AG04 | Etravirine (TMC 125). Former code: J05AG-ETV |
| J05AG-LOV | Loviride |
| J05AG05 | Rilpivirine (TMC-278). Former code: J05AG-RPV |
| J05AG01 | Nevirapine (VIRAMUN) |
| J05AG02 | Delavirdine (U-90152) (RESCRIPTOR) |
| J05AG03 | Efavirenz (DMP-266) (STOCRIN, SUSTIVA) |
| J05AR01 | Combivir (Zidovudine/Lamivudine) |
| J05AR02 | Kivexa (Lamivudine/Abacavir) |
| J05AR03 | Truvada (Tenofovir/Emtricabine) |
| J05AR04 | Trizivir (Zidovudine/Lamivudine/Abacavir) |
| J05AR05 | Douvir-N (Zidovudine/Lamivudine/Nevirapine) |
| J05AR06 | Atripla (Emtricitabine/Tenofovir/Efavirenz) |
| J05AR07 | Triomune (Stavudine/Lamivudine/Nevirapine) |
| J05AR08 | Eviplera/Complera (Emtricitabine/Tenofovir/Rilpivirine) |
| J05AR09 | Stribild (Emtricitabine/Tenofovir/Elvitegravir/Cobicistat) |
| J05AR10 | Kaletra/Aluvia (Lopinavir/Ritonavir) |
| J05AR11 | Lamivudine, tenofovir disoproxil and efavirenz |
| J05AR12 | Lamivudine and tenofovir disoproxil |
| J05AR13 | Lamivudine, abacavir and dolutegravir |
| J05AR14 | Darunavir and cobicistat |
| J05AX11 | Elvitegravir (Gilead). Former code: J05AX-EVG |
| J05AX-VIC | Vicriviroc (Schering) |
| J05AX07 | Enfurvirtide (Fuzeon , T-20) |
| J05AX08 | Raltegravir (Merck) |
| J05AX09 | Maraviroc (Pfizer) |
| J05AX12 | Dolutegravir |
| J05AX-CAB | Cabotegravir (GSK-744) |
| L01XX05 | Hydroxyurea/Hydroxycarbamid (Litalir) |
| V03AX03 | Cobicistat |

| **Code** | **Reason for Medication Stop** |
| --- | --- |
| 1 | Treatment failure (i.e. virological, immunological, and /or clinical failure) |
| 1.1 | Virological failure |
| 1.2 | Partial virological failure |
| 1.3 | Immunological failure – CD4 drop |
| 1.4 | Clinical progression |
| 1.5 | Resistance (based on test result) |
| 2 | Abnormal fat redistribution |
| 3 | Concern of cardiovascular disease |
| 3.1 | Dyslipidaemia |
| 3.2 | Cardiovascular disease |
| 4 | Hypersensitivity reaction |
| 5 | Toxicity, predominantly from abdomen/G-I tract |
| 5.1 | Toxicity – GI tract |
| 5.2 | Toxicity – Liver |
| 5.3 | Toxicity – Pancreas |
| 6 | Toxicity, predominantly from nervous system |
| 6.1 | Toxicity - peripheral neuropathy |
| 6.2 | Toxicity – neuropsychiatric |
| 6.3 | Toxicity – headache |
| 7 | Toxicity, predominantly from kidneys |
| 8 | Toxicity, predominantly from endocrine system |
| 8.1 | Diabetes |
| 9 | Haematological toxicity (anemia …etc.) |
| 10 | Hyperlactataemia/lactic acidosis |
| 11 | Bone toxicity |
| 15 | Social contra-indication |
| 16 | Contra-indication unspecified |
| 16.8 | Contra-indication expired |
| 16.9 | Contra-indication – other |
| 17 | MTCT regimen completed |
| 70 | Pregnancy - toxicity concerns (during pregnancy) |
| 75 | Pregnancy - switch to a more appropriate regimen for PMTCT |
| 88 | Death |
| 90 | Side effect - any of the above not mentioned |
| 90.1 | Comorbidity |
| 91 | Toxicity – other (not mentioned above) |
| 91.1 | Toxicity – unspecified |
| 92 | More effective treatment available |
| 92.1 | Simplified treatment available |
| 92.2 | Treatment too complex |
| 92.3 | Drug interaction |
| 92.31 | Drug interaction - commencing TB/BCG treatment |
| 92.32 | Drug interaction - ended TB/BCG treatment |
| 92.33 | Change in eligibility criteria (e.g. child old enough for tablets; refrigerator no longer available) |
| 92.4 | Protocol change |
| 92.5 | Regular treatment termination (used in tblMED e.g. for DAAs against HCV, antibiotics) |
| 92.6 | End of empiric therapy |
| 92.9 | Change in treatment not due to side-effects, failure, poor adherence or contra-indication |
| 93 | Structured Treatment Interruption (STI) |
| 93.1 | Structured Treatment Interruption (STI)-at high CD4 |
| 94 | Patient's wish/ decision, not specified above |
| 94.1 | Non-compliance |
| 94.2 | Defaulter |
| 95 | Physician’s decision, not specified above (note overlap with standard code) |
| 96 | Pregnancy |
| 96.1 | Pregnancy intended |
| 96.2 | Pregnancy ended |
| 97 | Study treatment |
| 97.1 | Study treatment commenced |
| 97.2 | Study treatment completed |
| 97.6 | Drug not available |
| 98 | Other causes, not specified above |
| 99 | Unknown |

|  |  |
| --- | --- |
| **Code** | **Reason for Medication Start** |
| 1 | PMTCT |
| 30 | ARV as treatment |
| 40 | PEP – Post Exposure Prophylaxis |
| 50 | PREP |
| 95 | Not ascertained |
| 99 | Unknown despite attempting ascertainment |

### tblART\_MUM (Antiretroviral Medication of mother in cases where mother is not enrolled in cohort)

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| CHILD\_ID | character (or numeric if possible) | Patient ID of the child (If child is not enrolled into care at an IeDEA site, enter mother’s ID with dashed numeric suffix such as [MOTHER\_ID]-1, [MOTHER\_ID]-2, etc. here) |
| ART\_ID | character. see coding table for valid codings. | Represents the antiretroviral treatment |
| ART\_SD (\_A) | yyyy-mm-dd | Date of initiation of treatment |
| ART\_ED (\_A) | yyyy-mm-dd | Date of stopping of treatment |
| ART\_RS | numeric see coding table for valid codings. | Reason for stopping treatment |
| ART\_RS2 | numericsee coding table for valid codings. | Additional reason for stopping treatment |
| ART\_RS3 | numeric see coding table for valid codings. | Additional reason for stopping treatment |
| ART\_RS4 | numeric see coding table for valid codings. | Additional reason for stopping treatment |
| ART\_FORM | numeric:  1 = Tablet/capsule  2 = Syrup/suspension  3 = Combination of 1 and 2  4 = Powder  5 = Subcutaneous  6 = Intravenous  7 = Intramuscular  9 = Unknown | What formulation of the drug was given? |
| ART\_COMB | numeric:  0 = Individual drug  1 = Part of a fixed-dose combination  9 = Unknown | Was the drug given as part of a fixed-dose combination? |
| ARTSTART\_RS | numeric: see coding table | Reason for starting/receiving ART |

### tblBAS (Basic Information)

**Relation to HICDEP**: HICDEP+

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| PATIENT | character (or numeric if possible) | Code to identify patient (Cohort Patient ID) |
| PROGRAM | Character | (Optional variable) Direct one-to-one link from the patient to their program |
| BIRTH\_D (\_A) | yyyy-mm-dd | Birth date |
| ENROL\_D (\_A) | yyyy-mm-dd | Date of enrolment into the cohort |
| GENDER | numeric:  1 = Male  2 = Female  9 = Unknown | Gender/sex (phenotypic sex at birth) |
| MODE | Numeric | Code for mode of infection see table “Code” below |
| NAIVE\_Y | numeric:  0 = No  1 = Yes  9 = Unknown | Is the patient ART-naïve upon enrollment? (i.e. no prior exposure to antiretroviral therapy for **treatment**) |
| PROPH\_Y | numeric:  0 = No  1 = Yes  9 = Unknown | Prior to enrollment, has the patient been exposed to antiretroviral therapy for prophylaxis such as PMTCT, PREP, or PEP? |
| RECART\_Y | numeric:  0 = No  1 = Yes  9 = Unknown | Has the patient ever received antiretroviral treatment? This includes all antiretroviral therapy given as **treatment** even if given by another center or program but excludes antiretroviral drugs given only for PMTCT or other prophylaxis. |
| RECART\_D (\_A) ~~HAART\_D (\_A)~~ | yyyy-mm-dd | Date of ~~ART start~~ first antiretroviral treatment initiation. Leave blank if ART not yet initiated. This should be the first date at which antiretroviral therapy, regardless of regimen, was given as **treatment** irrespective of whether it was given at this center/program or not. It excludes antiretroviral regimens given only for PMTCT or other prophylaxis. |
| AIDS\_Y | numeric:  0 = No  1 = Yes  9 = Unknown | Has patient ever been given an AIDS diagnosis? (i.e. WHO stage 3 or 4 or CDC category C diagnosis) |
| AIDS\_D (\_A) | yyyy-mm-dd | If yes, date of AIDS diagnosis |

|  |  |
| --- | --- |
| **Code** | **Mode of infection** |
| 1 | homo/bisexual |
| 2 | injecting drug user |
| 3 | (1+2) |
| 4 | haemophiliac |
| 5 | transfusion, non-haemophilia related |
| 6 | heterosexual contact |
| 7 | (6+2) |
| 8 | Perinatal |
| 9 | Sexual contact (homo/hetero not specified) |
| 10 | Sexual abuse |
| 90 | other, (specify) |
| 99 | unknown |

**tblCANC (Diagnosis of Cancer)**

**Relation to HICDEP**: HICDEP

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| PATIENT | character (or numeric if possible) | Code to identify patient (Cohort Patient ID) |
| CANC\_D (\_A) | yyyy-mm-dd | Date of diagnosis |
| LOC\_CODE | character (see partial coding table for NA-ACCORD-short list below) | Location code according to diagnosis |
| LOC\_CODE\_SYS | character | Location coding System: ICD10, ICD9, other systems; e.g., NA-ACCORD-short list (*suggest using NA-ACCORD-short list:* *NA-ACCORD\_Clinical\_DxICD9\_Mapping Update Sept 2014.xls*) |
| HIST\_CODE | character | Histology code according to diagnosis |
| HIST\_CODE\_SYS | character | Histology coding system: ICD-O-3, other systems, e.g. NA-ACCORD-short list, None (*suggest using NA-ACCORD-short list: NA-ACCORD\_Cancer\_Registry\_Dx\_Mapping Update Sept 2014.xls*) |

|  |  |
| --- | --- |
| **Location Code** | **Cancer Type** |
| 1 | Anal |
| 8 | Breast |
| 12 | Colon |
| 9 | Invasive cervical |
| 20 | Kaposi's Sarcoma |
| 33 | Lung |
| 39 | Non‐Hodgkin lymphoma |
| 51 | Other |
| 62 | Prostate |
| 64 | Skin: melanoma |
| 65 | Skin: non-melanoma |

### tblCENTER (Center Information)

**Relation to HICDEP**: HICDEP+

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| CENTER | character | Code for Clinic/Centre/Hospital where patient is seen. Needs to be unique within each region. |
| PROGRAM | character | Program with which the center is associated |
| NAME | character | Proper name to identify center |
| COUNTRY | character | 3-letter ISO code |
| PROVINCE | character | (Optional) Proper name to identify province |
| DISTRICT | character | (Optional) Proper name to identify district |
| CITY | character | (Optional) Proper name to identify city |
| GEOCODE\_LAT | Numeric | Latitude |
| GEOCODE\_LON | Numeric | Longitude |
| RURAL | numeric:  1 = Urban  2 = Mostly urban  3 = Mostly rural  4 = Rural  9 = Unknown | Code for the site situation (facility location) |
| LEVEL | numeric   1. Health centre 2. District hospital 3. Regional, provincial or university hospital   9 = Unknown | Code for level of care |
| ADULTPED | character:  “PED,” “ADULT”, or “BOTH” | Population the center serves |
| OPEN\_D | yyyy-mm-dd | (Optional) Date of opening of dataset: earliest date for which data were included from this site |
| CLOSE\_D | yyyy-mm-dd | Date of closing of dataset |
| ADD\_CENTER | yyyy-mm-dd | Inclusion date: date that the site was added to the cohort |
| DROP\_CENTER | yyyy-mm-dd | (Optional) Exclusion date: date that the site was dropped from the cohort |
| SURVEY\_INTERNET | numeric:  1 = sufficient access to complete online surveys  2 = degraded access making online survey completion difficult  3 = no internet access  9 = Unknown | Quality of Internet access for completing online surveys. |
| SURVEY\_PAPER | numeric  1 = site has resources to print and transfer surveys  2 = site has resources to print, but not to transfer surveys  3 = site does not have resources to print, but can transfer surveys  4 = site needs assistance in both printing and transferring surveys  8 = not applicable  9 = Unknown | Resources for printing and transferring paper surveys to a central location for data entry. |
| LAST\_REVIEWED\_D (\_A) | yyyy-mm-dd | Date when center data in this table was last reviewed and/or updated |

### tblDELIVERY\_CHILD (Delivery information related to child)

**Relation to HICDEP**: HICDEP+

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| MOTHER\_ID | character (or numeric if possible) | Patient ID of pregnant woman (mother of the child) |
| CHILD\_ENROL | numeric:  0=No  1=Yes  9=Unknown | Is child enrolled into care at an IeDEA site? |
| CHILD\_ID | character (or numeric if possible) | Patient ID of the child (If child is not enrolled into care at an IeDEA site, enter mother’s ID with dashed numeric suffix such as [MOTHER\_ID]-1, [MOTHER\_ID]-2, etc. here) |
| DELIV \_D (\_A) | yyyy-mm-dd | Date of delivery/birth |
| DELIV\_M | numeric:  1=Vaginally, spontaneous  2=Vaginally, forceps  3=Vaginally, vacuum  4=Vaginally, assisted (not further specified)  5=Vaginally, unknown  10= Cesarean section, primary/elective (before onset of labour and rupture of membrane)  11=Cesarean section, Secondary  12=Cesarean section (not further specified) | Mode of delivery |
| BREECH\_Y | numeric:  0=No  1=Yes  9=Unknown | Was the child born from a breech presentation? |

**tblDELIVERY\_MUM (Delivery information related to mother)**

**Relation to HICDEP**: HICDEP+

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| MOTHER\_ID | character (or numeric if possible) | Patient ID of pregnant woman (mother of the child) |
| PREG\_SEQ | numeric | Sequence number of the pregnancy for the specified mother |
| ROM\_DUR | numeric (metric: hours) , 999=unknown | Duration of rupture of membranes |
| ROM\_DUR\_A | character  ‘<’ = less than value specified  ‘>’ = greater than value specified  ‘=’ = value specified | Qualifier for duration of rupture of membranes (relates to value specified for ROM\_DUR) |
| DELIV\_LOCATION | numeric:  1=health facility  2=home  3=other  9=unknown | Location of Delivery |
| PLANNED\_HOME | numeric:  0=No  1=Yes  9=Unknown | If patient delivered at home, was it planned in advance? |
| DELIV\_ASSIST | numeric:  1=Doctor /Nurse/Midwife  2=Traditional Birth Attendant  3=Relative/Friend  4=No one  9=Unknown | Who assisted with the delivery? (If multiple, select response with the lowest associated numeric code) |
| TEAR\_Y | numeric:  0=No  1=Yes  9=Unknown | Episiotomy/tear |

### tblDIS (CDC-C and WHO Stage Diseases)

**Relation to HICDEP**: HICDEP+

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| PATIENT | character (or numeric if possible) | Code to identify patient (Cohort Patient ID) |
| DIS\_ID | Character. See coding table for valid codings | Code to identify event |
| DIS\_D (\_A) | yyyy-mm-dd | Start date of event  (Date of disease diagnosis) |
| DIS\_ED (\_A) | yyyy-mm-dd | End date of event  (If end date is available, disease outcome should be specified) |
| DIS\_WD | character, see coding table for valid codings | Means/Certainty of diagnosis |
| DIS\_OTH | character | Other location, only to be filled out if DIS\_ID code alone is not sufficient |
| DIS\_SITE | numeric  1=Abdominal  2=Bone/Joint  3=CNS/Meningeal  4=Genitourinary  5=Laryngeal  6=Lymphatic  7=Meningeal/CNS  8=Miliary  9=Pericardial  10=Pleural  88=Not applicable  95=Not ascertained  99=Unknown | Event site |
| DIS\_OUTCOME | numeric:  0 = Not evaluated  1 = Cured (lab confirmation)  2 = Treatment completed (but cure not confirmed)  3 = Treatment failed  4 = Died  5 = LTFU/default (from disease treatment (esp. TB), not necessarily from HIV clinic)  9 = Unknown | Disease outcome |

| **Codes** | **Description** |
| --- | --- |
| ANGC | Angular cheilitis |
| BCGD | BCG disease – disseminated |
| BCIR | Recurrent severe presumed bacterial infection (excluding pneumonia) |
| BCNE | Bacterial pneumonia, recurrent (>2 episodes within 1 year) |
| BLD | Unexplained anaemia (<8g/dl), and or neutropaenia (<500/mm3 – 2; <1000/mm3 - children), and or thrombocytopaenia (<50000/mm3) > 1 month |
| CANE | Candidiasis oesophogeal |
| CANM | Candidiasis (oral) (outside neonatal period) |
| CANO | Candidiasis (oesophogeal, trachea, bronchi or lungs) |
| CANT | Candidiasis (trachea, bronchi or lungs) |
| CLD | Chronic HIV-associated lung disease |
| CMO | HIV-associated cardiomyopathy |
| CMVO | Cytomegalovirus other location (site other than liver, spleen or lymph nodes) (onset at age>1month) |
| CMVR | Cytomegalovirus (CMV) chorioretinitis (onset at age>1month) |
| COCC | Coccidioidomycosis, disseminated or extrapulmonary |
| CRCO | Cryptococcosis extrapulmonary |
| CRSP | Cryptosporidiosis (duration > 1 month) |
| CRVC | Cervical cancer (invasive) |
| DEM | AIDS dementia complex |
| DIAC | Unexplained chronic diarrhoea (> 1month for adults; >14 days for children) |
| ENC | HIV encephalopathy |
| FBLS | Focal brain lesion |
| FEVC | Unexplained persistent fever (> 1 month) |
| FNIF | Fungal nail infections of fingers |
| HERP | Herpes simplex virus ulcers (duration > 1 month) or pneumonitis/esophagitis |
| HERPV | Visceral herpes simplex infection |
| HIST | Histoplasmosis extrapulm. |
| HZS | Herpes zoster (single dermatome) |
| ISDI | Isosporiasis diarrhoea (duration > 1 month) |
| KS | Kaposi Sarcoma |
| LEIS | Leishmaniasis visceral |
| LEU | Progressive multifocal leukoencephalopathy |
| LIP | Symptomatic lymphoid interstitial pneumonitis |
| LNTB | Lymph node tuberculosis |
| MC | Mycobacterium avium complex (MAC) or Kanasii extrapulm. |
| MCDI | Microsporidosis diarrhoea (duration > 1 month) |
| MCP | Mycobacterium tuberculosis pulmonary |
| MCPO | Mycobacterium pulmonary, other |
| MCX | Mycobacterium tuberculosis extrapulmonary |
| MCXO | Mycobacterium extrapulm. other (excluding BCG in children) |
| MNUM | Unexplained moderate malnutrition or wasting |
| MNUS | Unexplained severe malnutrition or wasting |
| MYCD | Any disseminated mycosis |
| NHG | Non-Hodgkin Lymphoma - not specified |
| NHGB | Non-Hodgkin Lymphoma – Burkitt (Classical or Atypical) |
| NHGI | Non-Hodgkin Lymphoma, diffuse large B-cell lymphoma (immunoblasti or centroblastic) |
| NHGP | Non-Hodgkin Lymphoma primary brain lymphoma |
| NHGU | Non-Hodgkin Lymphoma - Unknown/other histology |
| NPO | HIV-associated nephropathy |
| NUS | Acute necrotising ulcerative stomatitis, gingivitis or periodontitis |
| OHLP | Oral hairy leukoplakia |
| ORUL | Recurrent oral ulcerations |
| PCP | Pneumocystis carinii pneumonia |
| PGL | Persistent Generalized Lymphadenopathy |
| PPE | Papular pruritic eruptions |
| RTIR | Recurrent or chronic respiratory tract infection (RTIs, sinusitis, bronchitis, otitis media, otorrhea, pharyngitis) |
| SAM | Salmonella bacteraemia (non-typhoid) recurrent |
| SEBD | Seborrheic dermatitis |
| TOX | Toxoplasmosis brain (outside neonatal period) |
| WAST | HIV Wasting Syndrome |
| WTLM | Moderate unexplained weight loss (<10% of body weight) |
| WTLS | Severe unexplained weight loss (>10% of body weight) |

|  |  |
| --- | --- |
| **Code** | **Means/Certainty of diagnosis** |
| 1 | Definitive diagnosis |
| 2 | Presumptive diagnosis |
| 3 | Diagnosis from autopsy |
| 4 | Diagnosis from registry |

**tblLAB (Laboratory values)**

**Relation to HICDEP**: HICDEP+

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| PATIENT | character (or numeric if possible) | Code to identify patient (Cohort Patient ID) |
| LAB\_ID | character, see coding table for valid codings | Code representing the measurement |
| LAB\_D (\_A) | yyyy-mm-dd | Date of measurement/sample |
| LAB\_R | numeric:  1 = Positive (including trace, 1+, 2+, etc.)  0 = Negative  9 = Unknown/borderline | Measurement result |
| LAB\_V | numeric:  -1 = undetectable or detection limit as negative value | Value of measurement |
| LAB\_U | character or numeric, see coding table for valid codings | Unit of measurement |
| LAB\_FA | numeric:  0=No  1=Yes  9=Unknown | Was the sample taken while fasting? |
| LAB\_ST | character, see coding table for valid codings | Specimen type |

|  |  |
| --- | --- |
| **Code** | **Measurement** |
| A1C | Haemoglobin A1C |
| ACRA | Albumin Creatinine Ratio |
| ALB | Albumin |
| AFP | Alfa Fetoprotein |
| ALP | Alkaline Phosphatase |
| ALT | Alanine Aminotransferase |
| AMY | Amylase |
| AST | Aspartate aminotransferase |
| BIL | Total Bilirubin |
| BUN | Blood Urea Nitrogen |
| CD3 | CD3 |
| CD3P | % CD3 of leukocytes |
| CD8 | CD8 |
| CD8P | % CD8 of leukocytes |
| CHOL | Total Cholesterol |
| CL- | Cl- |
| CRE | Creatinine |
| DIPB | Dipstick result for blood in Urine |
| DIPG | Dipstick result for glucose in Urine |
| DIPK | Dipstick result for ketones in Urine |
| DIPLE | Dipstick result for leucocyte esterase in Urine |
| DIPP | Dipstick result for protein in Urine |
| GGT | Gamma-glutamyl transferase |
| GLUC | Glucose |
| HAEM | Haemoglobin |
| HDL | Serum HDL |
| HEMA | Hematocrit |
| IGRA | Interferon-Gamma Release Assay |
| INR | Quick/INR |
| LACT | Lactate |
| LDL | Serum LDL |
| LEUK | Leukocytes |
| LYM | Lymphocytes |
| LYMP | % Lymphocytes of leukocytes |
| MCV | MCV |
| NA+ | Na+ |
| NEU | Neutrophils |
| PCRA | Protein Creatinine Ratio |
| PHA | PH arterial |
| PHV | PH venous |
| PP | PP factor (II, VII, X) |
| PROT | Protein |
| PSA | Prostate-specific antigen |
| PTH | Parathyroid Hormone |
| PTR | Prothrombin rate |
| TBC | TB culture |
| TBM | TB smear/microscopy |
| TBHIST | TB histology |
| TBGX | TB GeneXpert |
| TBNAAT | TB NAAT/LPA (non-GeneXpert) |
| THR | Thrombocytes/platelets |
| TRIG | Serum Triglyceride |
| URA | Uric acid |
| UREA | Urea/Blood Urea Nitrogen |

|  |  |
| --- | --- |
| **Code** | **Unit String** |
| 1 | mmol/L |
| 2 | g/L |
| 3 | g/dL |
| 4 | mg/dL |
| 5 | IU/L (u/L) |
| 6 | µmol/L |
| 7 | INR |
| 8 | 1E+9/L |
| 9 | 1E+6/L |
| 10 | cells/µL |
| 11 | µkat/L |
| 12 | % |
| 13 | µg/L = ng/mL |
| 14 | mg/24h |
| 15 | mg/mmol |
| 16 | fl (Femtoliter) |
| 17 | µg/mL = mg/L |
| 99 | no units (e.g. for Dipstick results) |

It is recommended to use the string codes from the above table since this makes the data human readable.

|  |  |
| --- | --- |
| **Code** | **Specimen Type** |
| WB | Whole blood |
| P | Plasma |
| S | Serum |
| U24 | 24-hour urine |
| U | Urine |
| CSF | Cerebrospinal fluid |
| SP | Sputum |
| SA | Saliva |
| UNK | Unknown |
| OTH | Other |

### tblLAB\_BP (Laboratory values - Blood Pressure)

**Relation to HICDEP**: HICDEP

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| PATIENT | character (or numeric if possible) | Code to identify patient (Cohort Patient ID) |
| BP\_D (\_A) | yyyy-mm-dd | Date of Measurement |
| BP\_SYS | numeric | Systolic Blood Pressure |
| BP\_DIA | numeric | Diastolic Blood Pressure |
| BP\_U | numeric, see coding table for valid codings | Unit of measurement |

|  |  |
| --- | --- |
| **Code** | **Unit for blood pressure** |
| 1 | mmHg |
| 2 | cmHg |
| 3 | Kpa |

### tblLAB\_CD4 (CD4+ cell count tests)

**Relation to HICDEP**: HICDEP

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| PATIENT | character (or numeric if possible) | Code to identify patient (Cohort Patient ID) |
| CD4\_D (\_A) | yyyy-mm-dd | Date of measurement |
| CD4\_V | numeric -1 = undetectable or detection limit as negative value | Value of CD4 measurement |
| CD4\_U | numeric with codes:  1 = cells/µl  2 = % | Unit of measurement |

### tblLAB\_RES (Resistance Testing)

**Relation to HICDEP**: HICDEP+

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| PATIENT | character (or numeric if possible) | Code to identify patient (Cohort Patient ID) |
| TEST\_ID | character (or numeric if possible) | An arbitrary value identifying a resistance test result |
| SAMPLE\_D (\_A) | yyyy-mm-dd | Date of the actual sample taken (NOT the test date) |
| [SEQ\_DT](http://www.hicdep.org/wiki/Hicdep_1.90/TableLabRes/FieldSeqDt) (\_A) | yyyy-mm-dd hh:mm | Date and time when the sequencing was performed |
| [LAB](http://www.hicdep.org/wiki/Hicdep_1.90/TableLabRes/FieldLab) | character | Name of laboratory where the test was performed |
| [LIBRARY](http://www.hicdep.org/wiki/Hicdep_1.90/TableLabRes/FieldLibrary) | character | Library/algorithm used to identify resistance mutations |
| [REFSEQ](http://www.hicdep.org/wiki/Hicdep_1.90/TableLabRes/FieldRefseq) | character | Name/identifier of reference strain used to find mutations |
| [KIT](http://www.hicdep.org/wiki/Hicdep_1.90/TableLabRes/FieldKit) | character | Vendor and version/name of the kit used for the test |
| [SOFTWARE](http://www.hicdep.org/wiki/Hicdep_1.90/TableLabRes/FieldSoftware) | character | Software and version used to determine resistance |
| TESTTYPE | numeric:  1 = Genotype (e.g., GeneXpert, NAAT/LPA)  2 = Phenotype (e.g., culture)  9 = Other | Type of test |
| PATHOGENTYPE | character:  MeSH terminology <https://meshb.nlm.nih.gov/#/fieldSearch> | Type of pathogen |
| VIRUSTYPE | numeric:  1 = HIV  2 = HCV | Type of Virus |
| SUBTYPE | character | Subtype of HIV- or HCV-RNA |

### tblLAB\_RES\_LVL\_2 (Mutations)

**Relation to HICDEP**: HICDEP

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| TEST\_ID | character (or numeric if possible) | Identifier linking this record to [tblLAB\_RES](http://www.hicdep.org/wiki/Hicdep_1.90/TableLabRes) |
| GENE | character:  PRO = PRO sequence  RT = RT sequence  GP41 = GP41 sequence  GP120 = GP120 sequence | Type of sequence/gene (PRO, RT, GP41, GP120) |
| AA\_POS | numeric | Position of the mutation in the sequence |
| AA\_POS\_SUB | character:  a = first  b = second  etc. | Subposition used to code insertions |
| AA\_FOUND\_1 | character, empty = Amino acid has been deleted. | Mutation (Amino acid) found in the sequence |
| AA\_FOUND\_2 | character, empty = Amino acid has been deleted. | Mutation (Amino acid) found in the sequence (if more than 1) |
| AA\_FOUND\_3 | character, empty = Amino acid has been deleted. | Mutation (Amino acid) found in the sequence (if more than 2) |
| AA\_FOUND\_4 | character, empty = Amino acid has been deleted. | Mutation (Amino acid) found in the sequence (if more than 3) |

### tblLAB\_RES\_LVL\_3 (Resistance Test Result)

**Relation to HICDEP**: HICDEP

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| TEST\_ID | character (or numeric if possible) | Identifier linking this record to [tblLAB\_RES](http://www.hicdep.org/wiki/Hicdep_1.90/TableLabRes) |
| ATC\_CODE | character | [ATC code](http://www.whocc.no/atc_ddd_index/) of the medication |
| RES\_SCOR | character | Score of resistance or recommendation given from the test |
| RES\_SCOR\_ID | character:  S=sensitive  L=low level  I=intermediate  H=high level | Coded score of the resistance or recommendation given from the test |

### tblLAB\_RNA (Viral Assay)

Relation to HICDEP: HICDEP

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| PATIENT | character (or numeric if possible) | Code to identify patient (Cohort Patient ID) |
| RNA\_D (\_A) | yyyy-mm-dd | Date of measurement |
| RNA\_V | numeric (per microliter): -1 = undetectable or detection limit as negative value | HIV-RNA measurement value |
| RNA\_L | numeric | Lower Limit of HIV-RNA Assay |
| RNA\_T | Numeric (see coding table) | IF AVAILABLE, What type of VIRAL ASSAY was used for this measurement? |

|  |  |
| --- | --- |
| **Code** | **Viral assay used** |
| 5 | Roche TaqMan |
| 10 | Roche 1.0 |
| 15 | Roche 1.5 ultra-sensitive |
| 19 | Any Roche (unspecified) |
| 20 | NASBA |
| 21 | NASBA ultra-sensitive |
| 29 | Any NASBA (unspecified) |
| 31 | Chiron b-DNA 1.0 |
| 32 | Chiron b-DNA 2.0 |
| 33 | Chiron b-DNA 3.0 |
| 39 | Any Chiron (unspecified) |
| 40 | Abbott ultra-sensitive |
| 41 | Abbott LCx |
| 42 | Abbott RealTime HIV-1 m2000 |
| 50 | Monitor 1.0 |
| 51 | Monitor 1.0 ultra-sensitive |
| 55 | Monitor 1.5 |
| 56 | Monitor 1.5 ultra-sensitive |
| 59 | Monitor unspecified |
| 65 | Cobas 1.5 |
| 66 | Cobas 1.5 ultra-sensitive |
| 90 | Other |
| 99 | Unknown |

### tblLAB\_VIRO (Laboratory values – viro/serology)

Relation to HICDEP: HICDEP+

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| PATIENT | character (or numeric if possible) | Code to identify patient (Cohort Patient ID) |
| VS\_ID | character, see coding table for valid codings | Code representing the measurement |
| VS\_D (\_A) | yyyy-mm-dd | Date of measurement/sample |
| VS\_R | numeric:  1 = Positive  0 = Negative  9 = Unknown/borderline | Measurement result |
| VS\_V | Numeric | Measurement value (HCV-RNA & HBV-DNA only) (copies/ml) |
| VS\_U | numeric, see coding table for valid codings | Unit of measurement |
| VS\_ST | character, see coding table for valid codings | Specimen type |

|  |  |
| --- | --- |
| **Code** | **Viral test** |
| BVA | Bacterial vaginosis unspecified method |
| BVAC | Bacterial vaginosis – clinical |
| BVAG | Bacterial vaginosis - gram stain |
| CHLA | Chlamydia |
| CMVA | CMV antibodies |
| CRYP | Cryptococcal test – other/type unknown |
| CRAG | Cryptococcal antigen test (CrAg) |
| GONO | Gonorrhoea |
| HBV | Marker for hepatitis B infection (=HBVAC) - test unknown |
| HBVAC | HBV antibody (core) |
| HBVACIGM | HBV antibody (core IgM) |
| HBVACIGG | HBG antibody (core IgG) |
| HBVAE | HBV antibody (envelope) |
| HBVAS | HBV antibody (surface) |
| HBVD | HBV-DNA |
| HBVGE | HBV antigen (envelope) |
| HBVGS | HBV antigen (surface) |
| HCV | Marker for hepatitis C infection - test unknown |
| HCVA | HCV antibody |
| HCVG | HCV antigen |
| HCVBD | HCV b-DNA |
| HCVR | HCV-RNA |
| HDVA | Hepatitis delta antibody |
| HIV-1R | HIV-1 rapid test |
| HIV-1S | HIV-1 serology test (ELISA, Western Blot) |
| HIV-1DNA | HIV-1 DNA PCR test (qualitative) |
| HIV-2R | HIV-2 rapid test |
| HIV-2S | HIV-2 serology test (ELISA, Western Blot) |
| HIV-2DNA | HIV-2 DNA PCR test (qualitative) |
| HPV | Human Papillomavirus |
| MYCO | Mycoplasma |
| P24AG | P24 antigen |
| RUB | Rubella |
| STR | Streptococcus, group B |
| SYPHDV | Syphilis Direct Visualization (Darkfield microscopy) |
| SYPHSC | Syphilis Screening (RPR, VDRL) |
| SYPHCON | Syphilis Confirmatory (FTA-Abs, MHA-TB, TPPA, EIA) |
| TOXA | Toxoplasma antibodies |
| UREP | Ureaplasma |

|  |  |
| --- | --- |
| **Code** | **Unit String** |
| 1 | copies/mL |
| 2 | IU/mL |
| 3 | Geq (millions of genome equivalent) |

### tblLTFU (death and dropout)

**Relation to HICDEP**: HICDEP+

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| PATIENT | character or numeric | Code to identify patient (Cohort Patient ID) |
| DROP\_Y | numeric:  0 = No  1 = Yes | Has the patient dropped out? |
| DROP\_D (\_A) | yyyy-mm-dd | If patient has dropped out, Date of last visit |
| DROP\_RS | numeric, see coding table below | Reason for Drop |
| DEATH\_Y | numeric:  0 = No  1 = Yes | Has the patient died? |
| DEATH\_D (\_A) | yyyy-mm-dd | Date of Death |
| L\_ALIVE\_D (\_A) | yyyy-mm-dd | Last date of information for patient |
| MOTHERDEATH\_Y | numeric:  0 = No  1 = Yes  9 = Unknown | Has the patient’s biological mother died? |
| MOTHERDEATH\_D (\_A) | yyyy-mm-dd | Date of death of the patient’s biological mother |
| FATHERDEATH\_Y | numeric:  0 = No  1 = Yes  9 = Unknown | Has the patient’s biological father died? |
| FATHERDEATH\_D (\_A) | yyyy-mm-dd | Date of death of the patient’s biological father |

|  |  |
| --- | --- |
| **Code** | **Reason for Drop Out** |
| 0 | Patient was not infected (mainly for children) |
| 1 | Patient lost to follow-up / not known to be dead |
| 2 | Patient has not had visit within required amount of time |
| 2.1 | Patient did not respond to several invitations |
| 3 | Patient moved away |
| 3.1 | Patient moved to another country |
| 4 | Patient is followed by another centre |
| 4.1 | Paediatric patient transferred to adult care |
| 5 | Patient’s decision |
| 5.1 | Patient’s caretaker wanted to discontinue (for children) |
| 6 | Consent withdrawn |
| 7 | Incarceration/jail |
| 8 | Institutionalisation (drug treatment, psychological …etc.) |
| 9 | Other |

### tblMED (Other Medications)

**Relation to HICDEP**: HICDEP+

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| PATIENT | character (or numeric if possible) | Code to identify patient (Cohort Patient ID) |
| MED\_ID | character, see coding table for valid codings | ATC Code for drug |
| MED\_SD (\_A) | yyyy-mm-dd | Date of initiation of drug |
| MED\_ED (\_A) | yyyy-mm-dd | Date of stopping drug |
| MED\_RS | numeric, see coding table for valid codings{This list is identical to the stopping reasons for ART} | Reason for stopping drug |
| MED\_RS2 | numeric, see coding table for valid codings | Additional reason for stopping drug |
| MED\_RS3 | numeric, see coding table for valid codings | Additional reason for stopping drug |
| MED\_RS4 | numeric, see coding table for valid codings | Additional reason for stopping drug |
| MEDSTART\_RS | numeric  1 = Treatment(incl. for presumptive dx)  2 = Prophylaxis (primary or secondary)  9 = Unknown | Reason for starting medication (optional) |
| MED\_DO | numeric | Dosage (mg or mL) per intake unless MED\_FR=-1  (optional) |
| MED\_FR | numeric:  -1 = Frequency not known. MED\_DO contains dosage per day  0.33 = 1 dose every third day  0.5 = 1 dose every second day  1 = 1 daily dose/qd  2 = 2 daily doses/bid  3 = 3 daily doses/tid  4... = code gives number of daily doses | Frequency |
| DOT\_Y | numeric:  0 = No  1 = Yes  9 = Unknown/Not performed | Directly observed treatment  (optional) |

| **Codes Extended ATC[[1]](#footnote-1)** | **Other medication** |
| --- | --- |
| A10A | Insulin or derivatives hereof |
| A10B | Oral antidiabetic agents |
| A11CC | vitamin D |
| A14A | Anabolic steroids/appetite stimulants |
| B01AC | Anti-platelets |
| C-HYP | Other anti-hypertensive agents [C02, C03, C04, C07, C08] |
| C09 | ACE inhibitors |
| C10 | Lipid-lowering agents |
| G02CA | Tocolysis |
| H02 | Corticosteroids |
| J01 | Antibiotics |
| J01AA08 | Minocycline (MINOCIN) |
| J01EA01 | Trimethoprim (MONOTRIM, NOPIL) |
| J01EC02 | Sulfadiazine |
| J01EE | Cotrimoxazole - Comb. of sulfonamides and trimethoprim (BACTRIM, EUSAPRIM, NOPIL) |
| J01EE01 | Sulfamethoxazole and trimethoprim (Bactrim) |
| J01EE03 | Sulfametrole and trimethoprim - Cosoltrime (MADERAN) |
| J01FA09 | Clarithromycine (KLACID) |
| J01FA10 | Azithomycine (ZITHROMAX) |
| J01FF01 | Clindamycine (DALACIN) |
| J01GA01 | streptomycin |
| J01GB06 | Amikacine (AMIKINE) |
| J01MA02 | Ciprofloxacine (CIPROXINE, CILOXAN) |
| J01MA12 | Levofloxacin (TAVANIC) |
| J01MA14 | Moxifloxacin |
| J01RA02 | Cosoltrime (MADERAN) |
| J02AA01 | Amphotericin B (FUNGIZON) |
| J02AB | Imidazoles (DAKTARIN, NIZORAL, PEVARYL …) |
| J02AB02 | Ketoconazole |
| J02AC01 | Fluconazole (DIFLUCAN) |
| J02AC02 | Itraconazole (SPORANOX) |
| J02AC03 | Voriconazole |
| J02AC04 | Posaconazole |
| J02AC05 | Isavuconazole |
| J02AX01 | Flucytosine |
| J02AX04 | caspofungin |
| J04AB02 | Rifampin (RIMATICIN) |
| J04AB04 | Rifabutin (MYCOBUTIN) |
| J04AB05 | Rifapentine (Priftin) |
| J04AC01 | Isoniazide (RIMIFON) |
| J04AK01 | Pyrazinamide (PYRAZINAMID) |
| J04AK02 | Ethambutol (EMB, MYAMBUTOL) |
| J04AM05 | RIFATER |
| J04BA01 | Clofazimine (LAMPREN) |
| J04BA02 | Dapsone |
| J05AB01 | Aciclovir (ZIVORAX) |
| J05AB04 | Ribavirin |
| J05AB06 | Ganciclovir (CYMEVENE) |
| J05AB09 | Famciclovir |
| J05AB11 | Valaciclovir (VALTEX) |
| J05AB12 | Cidofovir (VISTIDE) |
| J05AB15 | Valganciclovir |
| J05AD01 | Foscarnet (FOSCAVIR) |
| J05AE11 | Telaprevir (INCIVEK, INCIVO) |
| J05AE12 | Boceprevir (VICTRELIS) |
| J05AE13 | Faldaprevir |
| J05AE14 | Simeprevir |
| J05AE15 | Asunaprevir |
| J05AF08 | Adefovir (PREVEON) |
| J05AF10 | Entecavir |
| J05AF11 | Telbivudine |
| J05AF12 | Clevudine |
| J05AR-DAAS | Daclatasvir/Asunaprevir |
| J05AX GRAZ-ELB | Grazoprevir/Elbasvir |
| J05AX14 | Daclatasvir |
| J05AX15 | Sofosbuvir |
| J05AX16 | Dasabuvir |
| J05AX65 | Ledipasvir/Sofosbuvir |
| J05AX67 | Ombitasvir, paritaprevir(ABT-450) and ritonavir |
| J07BM0 | HPV Vaccine |
| J07BM01 | HPV Vaccine (types 6, 11, 16, 18) |
| J07BM02 | HPV Vaccine (types 16, 18) |
| J07BM03 | HPV Vaccine (types 6, 11, 16, 18, 31, 33, 45, 52, 58) |
| L01AA01 | Cyclophosphamide (ENDOXAN) |
| L01AD02 | CCNU (LOMUSTINE) |
| L01AX04 | Dacabazine (DTIC - Dome) |
| L01BA01 | Methotrexate |
| L01CA01 | Vinblastin (VELBE) |
| L01CA02 | Oncovin (VINCRISTINE) |
| L01CB01 | Etoposide (VEPESIDE, EXITOP 100) |
| L01DB01 | Doxorubicine, Adriamycine (DOXIL, CAELYX, ADRIBLASTIN) |
| L01DC01 | Bleomycine |
| L01XB01 | Procarbazine (NATULAN) |
| L03AA02 | G-CSF/Filgastrim (NEUPOGEN) |
| L03AB | Interferons |
| L03AB-AL2 | Peginterferon alfa-2a/alfa-2b (PEGINTRON, PEGASYS) |
| L03AB10 | Peginterferon alfa-2b (PEGINTRON) |
| L03AB11 | Peginterferon alfa-2a (PEGASYS) |
| L03AC-IL2 | Interleukin 2 (PROLEUKIN) |
| M05BA | Bisphosphonate |
| N03A | Antiepileptics |
| N05A | Antipsychotics |
| N05CD | Benzodiazepine derivatives |
| N05CF | Benzodiazepine related drugs |
| N06A | Antidepressant |
| N07BC | Other drugs used in opioid dependence |
| N07BC01 | Buprenorphine |
| N07BC02 | Methadone |
| N07BC03 | Levacetylmethadol |
| N07BC04 | Lofexidine |
| N07BC51 | Buprenorphine, combinations |
| P01AX06 | Atovaquone (WELLVONE, MEPRONE) |
| P01BA03 | Primaquine |
| P01BD01 | Pyrimethamine (DARAPRIM) |
| P01BD51 | Pyrimethamine/Sulfadoxine (FANSIDAR) |
| P01CX01 | Pentamidine aerosol (PENTACARNET) |
| V03AB15 | Naloxone |
| V03AF03 | Folinate of calcium (LEUCOVORINE) |

### tblNEWBORN (Newborn Information)

**Relation to HICDEP**: HICDEP+

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| CHILD\_ID | character (or numeric if possible) | Patient ID of the child (If child is not enrolled into care at an IeDEA site, enter mother’s ID with dashed numeric suffix such as [MOTHER\_ID]-1, [MOTHER\_ID]-2, etc. here) |
| ENTRY\_PMTCT\_Y | numeric:  0=No  1=Yes  9=Unknown | Did the child enter your program through a PMTCT program/trial?  Note: Children can be considered to have entered through a PMTCT program if their mother received PMTCT drugs (either in a dedicated PMTCT program or an integrated program) and the infant was diagnosed in PMTCT follow-up and enrolled at <6 months of age. Enter 1 if child entered through a PMTCT program, 0 if child is known to have NOT entered through a PMTCT program (e.g. hospitalization, TB program, general HIV clinic) and 9 if unknown. |
| BREASTFD\_Y | numeric:  0=No  1=Yes  9=Unknown | Was the child ever breastfed? |
| BREASTFD\_DUR | numeric: number of weeks | For how many weeks was the child breastfed? |
| ABNORM\_Y | numeric:  0=No  1=Yes  9=Unknown | Did any abnormalities occur? (If yes, record in tblNEWBORN\_ABNORM) |

**tblNEWBORN\_ABNORM (Newborn Abnormalities)**

**Relation to HICDEP**: HICDEP+

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| CHILD\_ID | character (or numeric if possible) | Patient ID of the child (If child is not enrolled into care at an IeDEA site, enter mother’s ID with dashed numeric suffix such as [MOTHER\_ID]-1, [MOTHER\_ID]-2, etc. here) |
| ABNORM1 | numeric (see coding table) | Newborn abnormality |
| ABNORM2 | numeric (see coding table) | Newborn abnormality |
| ABNORM3 | numeric (see coding table) | Newborn abnormality |
| ABNORM4 | numeric (see coding table) | Newborn abnormality |
| ABNORM5 | numeric (see coding table) | Newborn abnormality |
| ABNORM\_S | character | further specification of abnormality |

|  |  |
| --- | --- |
| **Code** | **Newborn /Congenital abnormality** |
| 1.1 | Hydrocephalus |
| 1.2 | Microcephaly |
| 1.3 | Neural tube defects |
| 1.4 | Central Nervous System (CNS) - Other |
| 2.1 | Cleft lip and palate |
| 2.2 | Eye, Ear, Face and Neck - Other |
| 3.1 | Acyanotic defects *(e.g., ASD, VSD, AV canal, PDA)* |
| 3.2 | Cyanotic defects *(e.g. Tetralogy of Fallot, transposition, pulmonary atresia, truncus, Ebstein's)* |
| 3.3 | Heart - Other |
| 4.1 | Gastroschisis |
| 4.2 | Intestinal atresia |
| 4.3 | Tracheo-esophageal Fistula |
| 4.4 | Omphalocele |
| 4.5 | Anorectal malformation |
| 4.6 | Gastro-intestinal system - Other |
| 5.1 | Ambiguous genitalia |
| 5.2 | Hypospadias |
| 5.3 | Genitals - Other |
| 6.1 | Posterior urethral valves |
| 6.2 | Renal and urinary system - Other |
| 7.1 | Talipes equinovarus *(club foot)* |
| 7.2 | Limb defects – Other |
| 8.1 | Down syndrome |
| 8.2 | Chromosomal anomaly – Other |
| 9.1 | Other Organ System(s) Abnormality |

### tblOVERLAP (Cross-cohort identification)

**Relation to HICDEP**: HICDEP

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| PATIENT | character (or numeric if possible) | Code to identify patient (Cohort Patient ID) |
| COHORT | character | Code/name of the cohort |
| PAT\_OTH | character | Unique patient identifier in other cohort |
| COH\_OTH | character | Name of the other cohort |

### tblPREG (Pregnancy)

**Relation to HICDEP**: HICDEP+

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| MOTHER\_ID | character (or numeric if possible) | Patient ID of pregnant woman (mother of the child) |
| PREG\_SEQ | numeric | Sequence number of the pregnancy for the specified mother |
| MENS\_D (\_A) | yyyy-mm-dd | Start date of last menstrual period (If date not known exactly, please give approximated date) |
| EST\_CONCEPT\_D (\_A) | yyyy-mm-dd | Estimated date of conception. Derive in accordance with local norms based on ultrasound, date of last menstrual period (plus 2 weeks), fundal height, newborn exam/signs/symptoms, etc. |
| ANC\_D (\_A) | yyyy-mm-dd | Date of first antenatal care contact |
| PREG\_TEST\_D (\_A) | yyyy-mm-dd | Date of first positive pregnancy test |
| NUM\_FETUS | numeric | Number of fetuses |
| ULTR\_1 | numeric:  0=No  1=Yes, normal  2=Yes, abnormal  9=Unknown | Ultrasound 1. trimester (If >1 ultrasound during the first trimester, code as 2 if any are abnormal) |
| ULTR\_A\_1 | character | If abnormal ultrasound, please specify |
| ULTR\_2 | numeric:  0=No  1=Yes, normal  2=Yes, abnormal  9=Unknown | Ultrasound 2. trimester (If >1 ultrasound during the second trimester, code as 2 if any are abnormal) |
| ULTR\_A\_2 | character | If abnormal ultrasound, please specify |
| ULTR\_3 | numeric:  0=No  1=Yes, normal  2=Yes, abnormal  9=Unknown | Ultrasound 3. trimester (If >1 ultrasound during the third trimester, code as 2 if any are abnormal) |
| ULTR\_A\_3 | character | If abnormal ultrasound, please specify |

### tblPREG\_OUT (Pregnancy Outcome)

**Relation to HICDEP**: HICDEP+

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| MOTHER\_ID | character (or numeric if possible) | Patient ID of pregnant woman (mother of the child) |
| PREG\_SEQ | numeric | Sequence number of the pregnancy for the specified mother |
| CHILD\_ID | character (or numeric if possible) | Patient ID of the child (If child is not enrolled into care at an IeDEA site, enter mother’s ID with dashed numeric suffix such as [MOTHER\_ID]-1, [MOTHER\_ID]-2, etc. here) |
| OUTCOM | numeric:  4=Born alive  10=Stillborn  11=Spontaneous miscarriage  20=Termination: surgical  21= Termination: medication  22= Termination: method unknown | Pregnancy outcome |
| OUTCOM\_D (\_A) | yyyy-mm-dd | Date of birth or termination of pregnancy |
| B\_GAGEW | numeric | Gestational age in complete weeks at birth or termination |
| CHILD\_HIV | numeric  1=HIV exposed, status indeterminate  2=HIV infected  3=HIV uninfected | HIV status for a child not enrolled into HIV care |
| CHILD\_HIV\_D (\_A) | yyyy-mm-dd | Date associated with ascertainment of HIV status for child not enrolled into HIV care |

### tblPROGRAM (Linkage of Sites to Care Programs)

**Relation to HICDEP**: HICDEP

|  |  |  |
| --- | --- | --- |
| **Field** | **Format** | **Description** |
| PROGRAM | character | Program name |
| REGION | character  AP = Asia-Pacific  CA = Central Africa  CN = Caribbean, Central and South America  EA = East Africa  NA = North America  SA = Southern Africa  WA = West Africa | Region of Operation |

### tblVIS (Visit-related Information)

**Relation to HICDEP**: HICDEP+

| **Field** | **Format** | **Description** |
| --- | --- | --- |
| PATIENT | character (or numeric if possible) | Code to identify patient (Cohort Patient ID) |
| CENTER | character | Code for Clinic/Centre/Hospital where patient is seen. |
| VIS\_D (\_A) | yyyy-mm-dd | Date of patient visit |
| WEIGH | numeric: 999 = Unknown | Weight of patient at visit in kilograms (kg) |
| HEIGH | numeric: 999 = Unknown | Height/length of patient at visit in meters (m) |
| CDC\_STAGE | N, A, A1, A2, A3  B, B1, B2, B3  C, C1, C2, C3  9= Unknown | Clinical CDC stage at visit |
| WHO\_STAGE | numeric:  1 = WHO Stage I  2 = WHO Stage II  3 = WHO Stage III  4 = WHO Stage IV  9 = Unknown | Clinical WHO stage at visit |
| SMOKING\_Y | numeric:  0=No  1=Yes  9=Unknown | Is the patient currently a smoker? |
| PREG\_Y | numeric:  0=No  1=Yes  9=Unknown | Is the patient currently pregnant? If possible, provide additional details in tblPREG. |
| BREASTF\_Y | numeric:  0=No  1=Yes  9=Unknown | {*For infants and children only*}  Is the patient currently breastfeeding? |
| FEEDOTH\_Y | numeric:  0=No  1=Yes  9=Unknown | {*For infants and children only*}  Is the patient currently receiving foods or liquids other than breast milk? |
| CAREGIVER | numeric  1=Mother  2=Father  3=Sibling  4=Grandparent  5=Aunt or uncle  6=Self  7=Other family member  8=Other non-family member  9=Unknown  10=Other non-coded | {*For infants and children only*}  Who is the patient’s primary caregiver? |
| BROUGHT\_PATIENT | numeric  1=Mother  2=Father  3=Sibling  4=Grandparent  5=Aunt or uncle  6=Self  7=Other family member  8=Other non-family member  9=Unknown  10=Other non-coded | {*For infants and children only*}  Who brought the patient to this clinic visit? |
| HIV\_STATUS | numeric  1=HIV exposed, status indeterminate  2=HIV infected  3=HIV uninfected | {*For infants and children only*}  Current HIV status |
| STATUS\_KNOWN | numeric:  0=No  1=Yes  2=Disclosure ongoing  9=Unknown | {*For HIV-infected children and adolescents only*}  Does the patient know his/her HIV status? |
| SCHOOL | numeric:  0=No  1=Yes  9=Unknown | {*Optional for adult patients*}  Is the patient currently attending school or on break for customary school holidays? |
| SCHOOL\_LVL | numeric (see coding table) | {*Optional for adult patients*}  Current level of education  (ISCED97 refers to the ​1997 International Standard Classification of Education) |
| GENDER\_ID | numeric:  1=Male  2=Female  3=Transgender male  4=Transgender female  5=Other  9=Unknown | Current gender identification |

|  |  |
| --- | --- |
| **Code** | **Description** |
| 0 | none |
| 1 | primary education (ISCED97-1) |
| 2 | lower secondary (ISCED97-2) OR end of basic education |
| 3 | upper secondary or post-secondary non-tertiary (ISCED97 3 and 4) |
| 4 | university or post-graduate (ISCED97 5A and 5B) |
| 8 | other, only if none of the codes 0 to 4 applies |
| 9 | unknown |

### General Conventions

**Boolean Variables**

Generally, Boolean variables would end with the suffix \_Y and the convention (unless stated otherwise) is to use 0: No; 1: Yes, and 9: Unknown

**Date Specification of Precision**

*(Based on* [*HICDEP date conventions*](http://hicdep.org/wiki/Hicdep_1.50#Specificationofprecision)*)*

The format of YEAR-MONTH-DAY is best for precise dates, however, it might be that some cohorts are limited to representing date data at the level of the month or year only.

In case the date day is unknown, the date should be coded as the 15th of the month, so that 1999-12-?? becomes 1999-12-15. This enables the date to be no more than 15 days away from the actual date.

In case both the month and day are unknown, the date should be coded from the mid-point of the year, so that 1999-??-?? becomes 1999-07-01.

If the year is unknown but the presence of the date value is needed, a fictitious date should be used that couldn’t be mistaken with an actual date. An unknown year should be coded as 1911-11-11.

For issues regarding the precision of the dates, a character code is used to specify at which degree the day, month, or year date is precise. The annotation variable will have the same name as the date variable with the additional suffix \_A. For example, the precision of BIRTH\_D will be annotated using additional optional variables called BIRTH\_D\_A.

|  |  |
| --- | --- |
| **Character Code** | **Precision of date** |
| < | Before this date |
| D | Exact to the date |
| M | Exact to the month |
| Y | Exact to the year |
| > | After the date |
| U | Unknown |

During QA, it is the DHWG recommendation that malformed dates be treated as missing values

**Missing Values in Numerical Fields**

(pending discussion in DHWG)

**Revisions: February 15, 2013**

tblCENTER: no changes

tblBAS: RECART\_Y format changed to Boolean variables: 0: No; 1: Yes, 9: Unknown

tblLTFU: no changes

tblART: no changes

tblLAB\_RNA: no changes

tblLAB\_CD4: CD4\_V per microliter unit deleted

tblDIS: no changes

tblVIS: CDC\_STAGE categories added

**Revisions (comparing HICDEP 1.6): May 3, 2013**

tblCENTER: no changes

tblBAS: variable HIGH added to ‘Fields Omitted’

tblLTFU: no changes

tblART: “(ALT/Hepatitis)” removed from Coding Table ‘Reason for Stopping Treatment’ 5.2 Toxicity- Liver

tblLAB\_RNA: variable RNA\_T omitted as “new addition”

tblLAB\_CD4: no changes

tblDIS: DIS\_ID coding table (in IeDEA-DES ) dissimilar to DIS\_ID coding table in HICDEP 1.6. DIS\_ED now part of HICDEP (no more highlighted)

tblVIS: LIVEWITH, HEALTHY\_Y, HEIGH\_P, WEIGH\_P, HEADC, HEADC\_P, and BREASTF\_Y removed from ‘Fields Omitted’ table

**Updates: May 7, 2013 (by DHWG)**

tblLTFU.DEATH\_Y added (same as HICDEP)

tblLTFU.DROP\_Y added (same as HICDEP)

tblLTFU.LASTVISIT\_D dropped (can be computed from recently added tblVISIT)

tblLTFU.LAST\_INFO\_D renamed to tblLTFU.L\_ALIVE\_D (to be consistent with HICDEP, same semantics)

tblBAS.RECART\_Y renamed to tblBAS.NAIVE\_Y (slight different semantics, discussed in call)

created tblPROGRAM, add tblCENTER.PROGRAM, remove tblBAS.CENTER, added tblVISIT.CENTER, and (with one additional amendment during the call), add tblBAS.PROGRAM as optional variable

Recommend that malformed dates be treated as missing

Add tblCENTER.NAME (proper name to identify a center)

Add to tblCENTER four additional optional locations CITY, DISTRICT, PROVINCE, COUNTRY

Add tblCENTER.ADULTPED which can take “PED”, “ADULT”, or “BOTH”

**Update: September 12, 2013**

tblCENTER.COUNTRY: changed to ISO 3-letter code

**Update: May 6, 2014**

tblCENTER.CENTER needs to be unique within each region

tblCENTER.LEVEL added value 9 = “unknown”

new variables tblCENTER.OPEN\_D; tblCENTER.ADD\_CENTER; tblCENTER.DROP\_CENTER

**Update: February 2, 2015**

Removed yellow highlights – no more annotation of the delta from HICDEP

Added blue sections to indicated proposed items.

**Update: March 16, 2015**

Added new ART\_ID and RNA\_T codes.

Revised ART\_ID & ART\_RS codes to be consistent with HICDEP 1.8

Added additional reasons for stopping ART to tblART

Added 2 new codes for Mode of Infection (tblBAS)

**Update: April 14, 2015**

Corrected typos, accepted approved changes, updated list of tables in Appendix A wrt HICDEP 1.8

**Update: February 16, 2017**

Added the following tables: tblART\_MUM, tblCANC, tblDELIVERY\_CHILD, tblDELIVERY\_MUM, tblLAB, tblLAB\_BP, tblLAB\_RES, tblLAB\_RES\_LVL\_2, tblLAB\_RES\_LVL\_3, tblLAB\_VIRO, tblMED, tblNEWBORN, tblNEWBORN\_ABNORM, tblOVERLAP, tblPREG, tblPREG\_OUT

tblART: added ART\_FORM, ART\_COMB, ARTSTART\_RS

tblBAS: added PROPH\_Y, RECART\_Y, AIDS\_Y, AIDS\_D (\_A). Renamed HAART\_D (\_A) to RECART\_D (\_A) and clarified definition

tblCENTER: added SURVEY\_INTERNET, SURVEY\_PAPER, LAST\_REVIEWED\_D (\_A)

tblDIS: added DIS\_OTH, DIS\_SITE, DIS\_OUTCOME. Expanded disease code list to include pediatric and CDC classification codes

tblLTFU: added DROP\_D (\_A), DROP\_RS, MOTHERDEATH\_Y, MOTHERDEATH\_D (\_A), FATHERDEATH\_Y, FATHERDEATH\_D (\_A). Removed TRANSFER\_D (\_A).

tblVIS: added SMOKING\_Y, PREG\_Y, BREASTF\_Y, FEEDOTH\_Y, CAREGIVER, BROUGHT\_PATIENT, HIV\_STATUS, STATUS\_KNOWN, SCHOOL, SCHOOL\_LVL, GENDER\_ID

**Update: February 21, 2017**

Added page numbers.

1. Reference: <http://bioportal.bioontology.org/ontologies/ATC?p=classes&conceptid=root> [↑](#footnote-ref-1)